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From Sonographic Risk to Tissue Diagnosis: Diagnostic Performance of ACR TI-RADS in Thyroid Nodules with Radiology–Pathology Correlation

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Abstract

Background: ACR Thyroid Imaging Reporting and Data System (TI-RADS) provides standardized ultrasonographic risk stratification of thyroid nodules and assists in selecting lesions requiring pathological evaluation. This study assessed its diagnostic performance by correlating TI-RADS categories with pathological findings.

Methods: This prospective observational study included 51 patients with thyroid nodules evaluated at Rajalakshmi Medical College and Hospital, Pennalur, from June to December 2025. Nodules were classified according to ACR TI-RADS and correlated with FNAC and/or histopathological diagnosis. Diagnostic performance was evaluated using sensitivity, specificity, predictive values, and accuracy.

Results: Of 51 nodules, 35 (68.6%) were benign and 16 (31.4%) malignant. Malignancy rates were 0%, 7.1%, 33.3%, and 81.8% in TR2, TR3, TR4, and TR5 categories, respectively ($p<0.001$). Using TR4–TR5 as positive categories, sensitivity was 93.8%, specificity 60.0%, positive predictive value 51.7%, negative predictive value 95.5%, and diagnostic accuracy 70.6%. TR4–TR5 nodules had 22.5-fold higher odds of malignancy.

Conclusion: ACR TI-RADS provided effective malignancy risk stratification, with high sensitivity and negative predictive value. Radiology–pathology correlation improved diagnostic confidence and supported appropriate selection of nodules for invasive evaluation.

Keywords: ACR TI-RADS; Thyroid nodule; Ultrasonography; Thyroid malignancy; Histopathology.

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Introduction:

Thyroid nodules are frequently detected on ultrasonography, but only a minority are malignant, making accurate risk stratification essential to avoid unnecessary invasive procedures. The American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) provides a standardized ultrasound-based approach using nodule composition, echogenicity, shape, margin, and echogenic foci to estimate malignancy risk and guide fine-needle aspiration. Recent evidence has demonstrated significant concordance between ACR TI-RADS categories, Bethesda cytology, and final histopathological diagnosis, although diagnostic performance may vary across nodule categories and sizes [1, 2]. Studies have also shown that ACR TI-RADS can reduce unnecessary biopsies while maintaining clinically useful sensitivity for malignancy detection; however, occasional cancers may remain below biopsy thresholds [3]. Radiology–pathology correlation therefore remains important for validating its performance in individual clinical settings. The present study aimed to assess the diagnostic performance of ACR TI-RADS in predicting thyroid malignancy by correlating ultrasound categories with cytological and/or histopathological findings.

Methods:

Study was conducted in the departments of Radiodiagnosis and Pathology at Rajalakshmi Medical College and Hospital, Pennalur, from June 2025 to December 2025. Patients presenting with clinically suspected or incidentally detected thyroid nodules who underwent thyroid ultrasonography during the study period were consecutively enrolled after obtaining informed consent. Patients of either sex aged ≥18 years with one or more discrete thyroid nodules detected on ultrasonography and who subsequently underwent fine-needle aspiration cytology (FNAC) and/or surgical histopathological examination were included. Patients with diffuse thyroid disease without a definite nodule, previously diagnosed thyroid malignancy, prior thyroid surgery, inadequate cytological material, lesions without pathological confirmation, and patients unwilling to participate were excluded. Demographic and clinical information including age, sex, presenting complaints, duration of swelling, thyroid-related symptoms, previous thyroid disease, and relevant family history was recorded. All participants underwent high-resolution ultrasound examination of the thyroid using a high-frequency linear transducer. Each thyroid nodule was systematically assessed for maximum size, composition, echogenicity, shape, margin, and echogenic foci. Additional findings such as vascularity, extrathyroidal extension, multifocality, and suspicious cervical lymphadenopathy were also

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documented. Nodules were scored and categorized according to the ACR TI-RADS as TR1, TR2, TR3, TR4, or TR5 based on the total number of ultrasound feature points. Radiological assessment was completed before knowledge of the final pathological diagnosis to minimize interpretation bias.

Ultrasound-guided FNAC was subsequently performed for nodules meeting clinical or ACR TI-RADS-based indications using aseptic precautions. Cytological smears were prepared, appropriately stained, and evaluated by experienced pathologists. Cytological findings were classified according to the Bethesda System for Reporting Thyroid Cytopathology**,** ranging from Bethesda category I to VI. Patients with surgical indications subsequently underwent thyroidectomy or appropriate thyroid surgery, and excised specimens were fixed in 10% neutral-buffered formalin, processed routinely, sectioned, stained with hematoxylin and eosin, and examined histopathologically. For the primary analysis, nodules were classified as benign or malignant based on final histopathology whenever available; in non-operated patients, definitive cytological findings were considered for radiology–pathology correlation where appropriate. ACR TI-RADS categories were compared with cytological and histopathological diagnoses, and the proportion of malignant lesions within each TI-RADS category was calculated. Diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy of ACR TI-RADS for predicting thyroid malignancy. Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized using mean with standard deviation or median with interquartile range, as appropriate. Associations between TI-RADS category and pathological diagnosis were evaluated using the chi-square test or Fisher's exact test. Receiver operating characteristic analysis was performed where applicable, and a p-value <0.05 was considered statistically significant.

Results:

The study included 51 patients with thyroid nodules, of whom 35 (68.6%) had benign pathology and 16 (31.4%) had malignant lesions. ACR TI-RADS classification showed 8 (15.7%) nodules in TR2, 14 (27.5%) in TR3, 18 (35.3%) in TR4, and 11 (21.6%) in TR5. The proportion of malignant nodules increased progressively with increasing TI-RADS category, from 0% in TR2 and 7.1% in TR3 to 33.3% in TR4 and 81.8% in TR5. This association between TI-RADS category and pathological diagnosis was statistically significant (χ^2=20.51, p<0.001) (Table 1). When TR4 and TR5 were considered test-positive for malignancy, ACR TI-RADS correctly identified 15 of the 16 malignant lesions, yielding a sensitivity of 93.8%. Specificity was 60.0%, while the positive and negative predictive values were 51.7% and 95.5%, respectively. Overall diagnostic accuracy was 70.6%. Nodules classified as TR4–TR5 had approximately 22.5 times higher odds of malignancy compared with TR2–TR3 nodules (Fisher's exact p<0.001). The high sensitivity and negative predictive value demonstrated the usefulness of ACR TI-RADS for identifying nodules requiring further pathological evaluation (Table 2).

Discussion:

The present study demonstrated a strong relationship between increasing ACR TI-RADS category and pathological malignancy, supporting the usefulness of structured ultrasonographic risk stratification in patients with thyroid nodules. Among the 51 evaluated nodules, 16 (31.4%) were malignant, and the malignancy rate progressively increased from 0% in TR2 and 7.1% in TR3 to 33.3% in TR4 and 81.8% in TR5, with a statistically significant association between TI-RADS category and pathological diagnosis (p<0.001). This progressive increase is biologically and clinically plausible because ACR TI-RADS assigns increasing scores to ultrasound characteristics associated with malignancy, including solid composition, marked hypoechogenicity, taller-than-wide configuration, irregular or lobulated margins, and punctate echogenic foci. Dhar et al. [1], in an Indian tertiary-care study, demonstrated significant concordance between TI-RADS, Bethesda cytological classification, and final histopathology, emphasizing the complementary roles of radiology and pathology. Similarly, Huang et al. [4] found a marked increase in histologically confirmed malignancy among higher TI-RADS categories, with 71.4% of surgically excised TR5 nodules being malignant. Eissa et al. [2] also reported a significant relationship between higher ACR TI-RADS categories and malignant pathological findings and particularly highlighted microcalcification as an important malignant feature. The 81.8% malignancy rate observed among TR5 lesions in the present study therefore reinforces the concept that TR5 nodules warrant careful pathological evaluation. However, the overall malignancy prevalence in a hospital-based series may be greater than that expected in an unselected population because patients undergoing FNAC or surgery represent a clinically enriched group.

When TR4 and TR5 were considered positive for malignancy, ACR TI-RADS demonstrated 93.8% sensitivity, 60.0% specificity, 51.7% positive predictive value, 95.5% negative predictive value, and 70.6% overall diagnostic accuracy. The particularly high sensitivity and NPV suggest that lower-risk categories were useful for excluding malignancy, whereas the moderate specificity indicates that a considerable proportion of TR4–TR5

nodules remained benign. Zhang et al. [5], using TR4 or greater as the threshold, reported sensitivity of 85.4%, specificity of 37.5%, and accuracy of 72.5%, illustrating the same tendency toward greater sensitivity than specificity. Liu et al. [6] similarly reported a sensitivity of 86.7% but specificity of only 49.2% for conventional ACR TI-RADS. Large comparative evidence also supports its diagnostic value. Jin et al. [7], in 3,438 nodules, demonstrated an AUC of 0.844 and sensitivity of 89.1% for ACR TI-RADS, although unnecessary biopsy remained an important limitation. A meta-analysis by Kim et al. [8], including 67 studies and 76,512 nodules, found that ACR TI-RADS provided strong overall discriminatory performance, with the TR5 threshold producing particularly high specificity. The relatively lower specificity observed when TR4 and TR5 were combined in the present study is expected because lowering the positivity threshold captures more malignant lesions but simultaneously increases false-positive findings. This is demonstrated by the 14 benign nodules categorized as TR4–TR5 in the current series. Chen et al. [9] specifically investigated benign nodules classified as TR4 or TR5 and demonstrated that fibrosis, calcification, adenomatous hyperplasia, follicular epithelial hyperplasia, and Hashimoto thyroiditis could generate suspicious sonographic appearances. Fibrosis, for example, may produce a taller-than-wide configuration, while epithelial hyperplasia may create irregular margins or marked hypoechogenicity, thereby increasing TI-RADS scores despite benign histology.

The present study additionally showed that TR4–TR5 nodules had approximately 22.5-fold higher odds of malignancy than TR2–TR3 nodules, confirming the clinical value of ACR TI-RADS as a practical triage tool rather than as a replacement for pathological diagnosis. Angelopoulos et al. [3] demonstrated that ACR TI-RADS retained useful discriminatory performance even in larger thyroid nodules and emphasized the importance of combining ultrasound risk category with clinical and pathological assessment. An important strength of ACR TI-RADS is its standardized lexicon, which facilitates communication between radiologists, pathologists, surgeons, and endocrinologists and helps determine which nodules require FNAC or surveillance. Nevertheless, ultrasound interpretation remains partly operator dependent. Li et al. [10], in a systematic review and meta-analysis, reported only moderate overall inter-reader agreement for ACR TI-RADS, with agreement being particularly limited for nodule margins and echogenic foci. These observations highlight the importance of adequate radiologist training and standardized image acquisition. Furthermore, the modest sample size of 51 patients and single-centre nature of the present study limited the precision and generalizability of the diagnostic estimates, while selection of patients who underwent cytological or histopathological evaluation could have increased the apparent prevalence of malignancy. Cytology may also be indeterminate in Bethesda III and IV lesions, making surgical histopathology the most definitive reference standard. Despite these limitations, the strong increase in malignancy across TI-RADS categories, high sensitivity and NPV, and significant radiology–pathology association support routine ACR TI-RADS use for thyroid nodule assessment. Combining standardized ultrasound classification with FNAC/Bethesda reporting and histopathology where indicated provides a rational multidisciplinary approach that can identify high-risk lesions while potentially reducing unnecessary invasive evaluation of low-risk nodules.

Conclusion: ACR TI-RADS demonstrated good diagnostic performance for stratifying thyroid nodules according to malignancy risk. Malignancy increased progressively across higher TI-RADS categories, with TR5 nodules showing the highest malignant proportion. Considering TR4 and TR5 as positive categories, the system achieved high sensitivity and negative predictive value, indicating its usefulness for identifying nodules requiring further evaluation and for excluding malignancy in lower-risk lesions. However, the moderate specificity and positive predictive value highlight that ultrasound classification cannot replace pathological confirmation. Integration of ACR TI-RADS with FNAC, Bethesda cytology, and histopathology provides a reliable multidisciplinary approach for appropriate investigation and management of thyroid nodules.

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Table 1: Correlation between ACR TI-RADS category and pathological diagnosis; n (%)

ACR TI-RADS category	Total	Benign	Malignant	Malignancy rate (%)
TR2	8 (15.7)	8 (100.0)	0 (0.0)	0
TR3	14 (27.5)	13 (92.9)	1 (7.1)	7.1
TR4	18 (35.3)	12 (66.7)	6 (33.3)	33.3
TR5	11 (21.6)	2 (18.2)	9 (81.8)	81.8
Total	51 (100)	35 (68.6)	16 (31.4)	31.4

There was a significant association between increasing ACR TI-RADS category and malignancy (χ^2=20.51, df=3, p<0.001).

Table 2: Diagnostic performance of ACR TI-RADS for predicting malignancy using TR4–TR5 as a positive test

Parameter	Value
True positive	15
False positive	14
True negative	21
False negative	1
Sensitivity	93.80%
Specificity	60.00%
Positive predictive value	51.70%
Negative predictive value	95.50%
Diagnostic accuracy	70.60%
Odds ratio for malignancy, TR4–TR5 vs TR2–TR3	22.5
Fisher's exact test	p<0.001